



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|---------------------|------------------|
| 10/609,206 | 06/26/2003 | Daniel J. Potter | 0B-044600US | 7328 |
| 55962 | 7590 | 11/25/2008 | | |
| SJM/AFD-WILEY | | | | |
| 14901 DEVEAU PLACE | | | | |
| MINNETONKA, MN 55345-2126 | | | | |
| EXAMINER | | | | |
| YABUT, DIANE D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3734 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 11/25/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/609,206

Applicant(s)

POTTER ET AL.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 08/01/2008.

The examiner acknowledges the amendments made to the claims.

Claims 1-25 have been cancelled. Claims 26-44 are pending in this application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 26-31, 34-37, 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by McBroom et al., hereinafter "**McBroom**" (U.S. Patent No. **6,277,108**). Claims 26-31, 34-37, 40-44: McBroom discloses providing an introducer sheath including a sheath body **140**, the sheath body having a distal end and including a longitudinally extending sheath score line ("weakened portion") running along a length of the sheath body, and a tearable, contiguous radiopaque ring **160** or **500** abutting a distal end of said sheath body (just proximate of the distal tip of the sheath), the radiopaque ring defining an unfilled score line ("perforated line") **512** running along which the radiopaque ring may be broken by tearing, and being aligned with said sheath score line ("as the sheath **140** is severed, the marker band **160** is also severed"). The radiopaque ring score line may be located on the interior or exterior of the sidewall, wherein the thickness of the sidewall is reduced, and the radiopaque ring may also be

bonded to an inner wall of the sheath body. Bonding the radiopaque ring to the distal end of the sheath body may be achieved by thermoforming or adhesive without introducing polymer or binding agent into the at least one radiopaque score line, such as when the radiopaque ring is bonded to an outside wall of the sheath body and the score lines are located on the exterior of the sidewall. The introducer sheath is introduced into and manipulated through a patient's vasculature. See abstract, Figures 1 and 6-7; col. 1, lines 38-41, col. 3, line 54 to col. 4, line 14, and col. 5, lines 3-34.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 32-33 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**).

Claims 32-33: McBroom does not expressly disclose at least one radiopaque ring score line comprising at least one V-shaped or U-shaped notch. However, McBroom recognizes that the type of score lines can vary (col. 5, lines 27-28), and according to Merriam-Webster's Online Dictionary, "notch" is defined as a "V-shaped indentation" or "a rounded indentation," and therefore it would have been obvious to one of ordinary skill in the art at the time of invention to vary the shape of the score line or notch of the device of McBroom to facilitate tearing.

Claims 38-39: In addition, McBroom does not expressly disclose sonically or chemically bonding the radiopaque ring to the distal end of the sheath body. However, McBroom suggests that the ring may be fixed to the sheath in a number of manners (col. 4, lines 61-62), and therefore it would have been obvious to one of ordinary skill in the art to bond the ring to the sheath using a number of well-known techniques in the art, which would include sonic or chemical bonding.

Response to Arguments

5. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.
6. Applicant's arguments filed 08/01/2008 have been fully considered but they are not persuasive.
7. Applicant argues that McBroom does not teach that the radiopaque ring apertures and/or perforations are unfilled, since sheath material is permitted to at least partially fill the apertures and/or perforations during manufacture. Although this is true for one embodiment, McBroom also anticipates other configurations wherein the apertures may be maintained as weakened, unfilled surfaces to allow the marker to be splittable. For instance, the invention of McBroom suggests that unfilled score lines may be achieved after bonding the sheath to the ring by thermoforming or adhesive when the ring is disposed within the sheath and the score lines are formed on the interior of the ring, or conversely when the ring is disposed on the outside surface of the sheath and the score lines are formed on the exterior of the ring. In other words, the

score lines or apertures/perforations on the radiopaque ring appear to be only filled in with polymer or binding agent in the embodiments when the apertures are directly abutting the sheath surface. It is inherent that the perforations in these other embodiments should remain unfilled in order to permit severability along the score lines.

8. Applicant also argues that McBroom does not teach the marker band being split by tearing, but rather by the use of a slitter. However, the examiner believes the invention of McBroom still reads on this limitation since "tearing" may be construed as "lacerating" or "removing by any force or effort," which is achieved by a slitter. McBroom also recognizes that there are other techniques well known in the art other than the use of a slitter to separate the sheath and marker into two or more components (col. 3, lines 62-64).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731